

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed June 10, 2009 and the Advisory Action mailed August 31, 2009. Currently, claims 22-38 and 42-47 remain pending of which claims 34-38 were previously withdrawn. The Examiner has apparently provisionally withdrawn claims 43-47, as a restriction requirement involving those claims has not been resolved. Claim 4, canceled in an amendment filed October 10, 2006, appears to have been erroneously listed as pending. Claims 22-33 and 42 have been rejected. Claims 22, 43, 45, and 47 have been amended to clarify the relationships among the elements. Claim 44 has been canceled. No new matter has been introduced.

Restriction

In the communication of July 28, 2009, the Applicant requested reconsideration of a new restriction request presented with a Final Office Action. The Examiner has not yet done so, the restriction requirement has not been repeated and made final, and an office action has not been presented on the claims to the invention elected.

“Where the initial requirement is traversed, it should be reconsidered. If, upon reconsideration, the examiner is still of the opinion that restriction is proper, it should be repeated and made final in the next Office action.” (37 CFR §1.143; MPEP 810.03; MPEP 821.01)

Although the Examiner did not formally identify the separate inventions to which the restriction applied, it was and is believed that it was the Examiner’s intent to identify:

Invention I, corresponding to claims 22-38, drawn to a cross-linked gelatin sponge and a wetting agent which is soluble in a non-aqueous solvent.

Invention II, corresponding to claims 43-47, drawn to a delivery system comprising the cross-linked gelatin sponge of claim 22, a saline solution, and a syringe.

The Examiner’s assertion in the Advisory Action that the Applicant has attempted to shift the invention from the initially presented Invention I to Invention II is believed to be incorrect. Instead, the Applicant requested that the restriction between Invention I and invention II be withdrawn.

Contrary to the Examiner's assertion that it can be shown that they are not disclosed as capable of use together, the delivery system of Invention II includes and therefore is capable of delivering the sponge of Invention I. Thus they are specifically capable of use together. The delivery system is believed to be necessary to the utilization of the sponge given the very short (2-3 seconds) hydration times associated with the inventive composition of Invention I which would appear to preclude other commonly means of deploying a hydrating sponge. Since the delivery system of Invention II includes the sponge of Invention I, both employ a non-aqueous solvent soluble wetting agent which decreases the hydration time of the sponge and they are believed to share a mode of action and to be not independent and distinct. The Examiner had earlier adopted the position that the kit (delivery system) is an obvious variant. The current restriction requirement is new and was not made final.

Applicant provisionally elected Invention II with traverse. As noted earlier, the Examiner appears to have misread the amended claim as it has been asserted that claim 22, as amended, requires a non-aqueous solution which is not the case. The composition of current claim 22 only requires that the wetting agent be soluble in a non-aqueous solvent, not that the solvent be present in the composition. There is no solution recited in claim 22. The amendment to claim 22 properly returned the claim to a composition by removing the solution in response to the Examiner's rejection under §112. Similarly, there is no solution recited in claim 43. Thus claim 22 corresponds to the earlier presented invention with an additional limitation as to a characteristic which the wetting agent must possess and claim 43 presents a kit in which the composition of claim 22 is an element.

Further, the Examiner has repeated in the Advisory Action, mailed August 31, 2009, the belief that the Applicant "arguments are directed to a method of making the product, while the present claims are directed to a product by process". Applicant respectfully disagrees with both assertions. There is no method or process language recited in the claims as originally presented or as currently amended. Instead, the claims recite a composition comprising a gelatin sponge and a wetting agent, wherein the wetting agent is characterized by being soluble in a non-aqueous solvent, whether or not

the non-aqueous solvent is employed in forming the composition, and further wherein the wetting agent decreases hydration time of the gelatin sponge.

Applicant again traverses the newly presented restriction requirement; requests that the new restriction requirement be withdrawn; and awaits an Office action on the new and amended claims.

Claim Rejections – 35 USC § 112

Claims 22-33 and 42 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection asserts that the claims as amended ‘recite: “a non-aqueous solvent is used to dissolve the wetting agent” has introduced new matter”. As noted above, claim 22 was amended to address the rejection and the rejection is now considered moot.

Further with regard to the assertion that new matter has been introduced, the paragraph at page 11, lines 18-27 (paragraph [0055] of the published application), discloses that the wetting agent may be dissolved “in a non-aqueous liquid solvent (e.g., ethanol, isopropanol, acetone, and the like)” prior to incorporation into the foam or applied as a coating to the foam. This appears to be an unambiguous statement that the wetting agent is soluble in a non-aqueous liquid solvent. In both of the cited, but nonlimiting, incorporation methods, the liquid solvent is then “removed by evaporation” and so is not present in the claimed resulting composition.

Further still, the Examiner appears to have misinterpreted the information presented earlier with respect to page 23, line 1 to page 24, line 28 (paragraphs [0119]-[0122]) disclosing that for four wetting agents, which share the recited property of being soluble in non-aqueous solvents, ethanol and isopropanol. The results do not depend upon which of the two non-aqueous solvents is used to incorporate the wetting agent into the composition, but reflect the uniform utility of the selected wetting agents in decreasing hydration times. Thus the resulting compositions are substantially equivalent in performance following the removal of the solvent (paragraph [0117]). The cited text was presented in support of the wetting agent being soluble in those solvents. It is believed that the text provides adequate support for the wetting agent used in the

composition of claims 22 and 43 being soluble in ethanol or isopropanol and so the claimed invention meets the requirement of §112.

However the Examiner stated: "Non-aqueous solvent used for the purpose of measuring hydration time of compositions having different wetting agent." (sic) The non-aqueous solvents in question were not used for the purpose of measuring hydration times. They were used in the preparation of compositions which were then dried to remove the non-aqueous solvent. Subsequent hydration testing (with water) indicated that the enhanced performance seen in those dried compositions did not depend upon the non-aqueous solvent used in the preparation of the compositions, but rather upon the presence of the wetting agents having the recited properties.

The Examiner then continued: "Applicants themselves admit that the data demonstrates that there is no appreciable difference between aqueous and non-aqueous solvent in the hydration time of the coated crosslinked gelatin." Applicant respectfully disagrees with the Examiner's characterization of the example. The testing indicates no appreciable difference between wetting agent/solvent combinations used during incorporation, said wetting agents individually being soluble in a non-aqueous solvent, which were incorporated using one of two non-aqueous solvents. There is no comparison in the cited text between aqueous and non-aqueous solvent used in the preparation of the composition. The text at paragraph [0122] indicates that wetting agents which are soluble in non-aqueous solvents have previously unrecognized advantages with respect to avoiding irreversible damage to the foam during preparation of the composition. As noted earlier, hydration times of the resulting solvent-free compositions are decreased from 8 minutes to 2-3 seconds by the addition of the selected wetting agents to a substantially undamaged foam. (Table 5.)

For at least these reasons, it is believed that adequate support exists in the specification for compositions comprising gelatin sponges formulated in combination with wetting agents, said wetting agents being soluble in non-aqueous solvents. Support is also provided for the advantage that such wetting agents provide with respect to decreasing hydration times when compared to sponges which do not include the wetting agents. Applicant respectfully requests that the Examiner withdraw the rejections.

Claim Rejections – 35 USC § 103

Claims 22-29, 31, and 42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yasushi et al. (JP 02-182259), herein after Yasushi, in view of EP 5568 334, believed to be Song et al. (EP 0 568 334), hereinafter Song. If this belief is incorrect, the Examiner is invited to provide the correct reference for consideration, preferably identifying the reference in the form specified by 37 CFR § 1.104 (d). After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03).

As acknowledged by the Examiner in the final Office Action, nowhere does Yasushi explicitly teach: “non-aqueous solvent in the composition as required by claim 22”. As discussed above, claims 22 and 43, as amended, do not include that limitation, but rather require that the wetting agent have two characteristics: “decreases hydration time of the gelatin sponge; and the wetting agent is soluble in a non-aqueous solvent”. Nowhere does Yasushi appear to disclose those limitations. Instead, Yasushi appears to disclose a surfactant that functions to stabilize a foamed precursor to a gelatin foam prior to and during a freeze-drying dehydration step. For this reason, Yasushi appears to teach producing a foam which necessarily includes the surfactant responsible for forming a stable foam and so the surfactant cannot be shown to decrease the hydration time of the resulting sponge. The hydration time associated with a sponge produced by the surfactant-based foaming process of Yasushi appears to be, at best, identical to the resulting foam containing the surfactant.

Yasushi subsequently employs a solvent which is characterized as able to dissolve a cross-linking agent. The preferred solvent is said to be an unspecified alcohol. The sponge of Yasushi is then said to be “immersed in an organic solvent solution of a crosslinking agent” for a period of several minutes to several hours. (Paragraph bridging pages 6 and 7.) One of ordinary skill in the art would appreciate that Yasushi teaches the residual surfactants in question may be extracted from the sponge by an alcohol during this soaking step. If the surfactant of Yasushi is soluble in a non-aqueous solvent, it

would appear to be present in the resulting sponge at a lower level than in the initially produced freeze-dried foam. In the absence of test data, one of ordinary skill in the art would expect the resulting cross-linked foam to have an undesirably increased hydration time compared to the initially produced foam.

The surfactant does not appear to meet the selection criteria for the wetting agent recited in claims 22 and 43 for the reason that the only hydration times which appear to measurable include the surfactant in the sponge. Thus the recited decrease upon incorporation of a wetting agent does not appear to occur in the sponge produced by the method of Yasushi. Further, there is nothing in Yasushi which appears to suggest that the addition of a wetting agent to the composition of Yasushi's foamed sponge would decrease the hydration time or that the incorporation of a surfactant in the precursor to be foamed to produce the sponge of Yasushi necessarily decreases the hydration time of a hypothetical foam which might be produced without the surfactant by a process not disclosed by Yasushi.

Further, nowhere does Song appear to disclose "wherein the wetting agent decreases hydration time of the gelatin sponge and the wetting agent is soluble in a non-aqueous solvent". Instead, Song appears to disclose the use of ethanol as a drying agent. The composition of claims 22 and 43 do not include an organic solvent or a drying step involving a drying agent. Nothing in either Yasushi or Song appears to suggest that more rapid drying would alter the hydration time or that the addition and removal of ethanol would provide a wetting agent within the composition that decreases the wetting time. Accordingly, Song appears to disclose a drying process not found in the pending claims and does not appear to overcome the deficiencies of Yasushi with respect to either a wetting agent which is characterized by being soluble in a non-aqueous solvent or with respect to decreasing the hydration time as a result of the presence of a wetting agent having that property. Nothing in Yasushi, Song, or a combination thereof appears to teach that the presence of any surfactant or wetting agent which may be present decreases the hydration time relative to a sponge of the same composition absent the surfactant or wetting agent as recited in the pending claims.

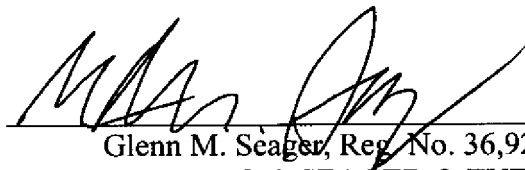
Accordingly, for at least these reasons, Applicants believe claims 22 and 43, to be allowable over Yasushi in view of Song and request that the rejection be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03) For at least this reason, Applicants respectfully request that the rejections of dependent claims 23-29, 31, and 4-47 be withdrawn.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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